

# The effect of collagen supplementation on human tendon protein synthesis

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53210

### Source

ToetsingOnline

### Brief title

Collagen for tendon remodelling

## Condition

- Tendon, ligament and cartilage disorders

### Synonym

Healthy tendon and injured anterior cruciate ligament protein synthesis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** HAN University of Applied Sciences

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Collagen, Protein, Remodelling, Tendon

## Outcome measures

### Primary outcome

Assess the impact of collagen supplementation on healthy tendon protein synthesis in otherwise healthy individuals (18 - 40 y) scheduled for ACL-surgery.

### Secondary outcome

Assess the impact of collagen supplementation on injured ligament and healthy muscle protein synthesis, based on ligament and muscle tissues that also become available during the ACL-surgery.

## Study description

### Background summary

Tendons transfer the force exerted by the corresponding muscle to bones and, therefore, are vital components of human locomotion. Tendon injury is very common, both in athletes as the general population. Once injured, tendons recover very poorly, resulting in a decrease in quality of life for the patient and a substantial burden on the health care system. Therefore, interventions that can aid in the prevention or treatment of tendon injury are warranted. The growth of all tissues, including tendon, is regulated by the net difference between protein synthesis and protein breakdown rates. Protein ingestion stimulates protein synthesis. Collagen is the main protein in human connective tissues, including tendon. The amino acids glycine and proline are the main building blocks of endogenous collagen and vitamin C serves as a co-factor in the synthesis and release of novel collagen proteins. Hence, dietary collagen may be the preferred protein source to deliver high amounts of glycine and proline and, together with vitamin C, maximize collagen synthesis in tendon. However, no evidence is available on the effect of vitamin C enriched collagen supplementation on human tendon protein synthesis.

### Study objective

The main objective of the current study is to assess the impact of dietary collagen supplementation on human tendon protein synthesis.

## **Study design**

Double-blind, randomized trial with two parallel groups.

## **Intervention**

All participants will be randomly assigned to the intervention or control group. The intervention group will receive:

- Collagen supplementation: The vitamin C-containing collagen supplement (20 g per dose) will be ingested as drink (100 mL of water mixed with 20 g of collagen powder) twice daily, once at breakfast and once before sleep.

The control group will receive:

- Placebo: Vitamin C-enriched maltodextrin will be used as an isocaloric placebo.

All participants will receive:

- Co-intervention: Short (5 min) hamstring or quadriceps exercise will be performed by all participants, 30 - 60 minutes following test drink ingestion.

All participants will also ingest a small dose (20 mL) of deuterium oxide daily, for the measurement of tissue protein synthesis.

## **Study burden and risks**

The burden and risks involved in participating in this experiment are limited. Participants need to ingest a test drink twice daily (100 mL per dose), need to perform 5 minutes of low intensity exercise twice daily, need to ingest deuterium oxide (20 mL) daily, and need to obtain a saliva sample daily, for seven days. The ingestion of deuterium oxide has been applied in numerous published studies and is entirely safe and non-toxic in the amounts provided in the present study. Tissue collection will occur during ACL-surgery, which is already planned as part of the participants\* course of treatment. A graft of the hamstring or quadriceps tendon will be used for ACL reconstruction, and a sample will be obtained under anesthesia during the standard surgical procedure. The tissue is extracted during the standard procedure, meaning that patients will not take on any extra burden by participating in this study. Two additional blood samples (2 x 10 mL) will be obtained before and after the experimental period.

The data attained within this study may improve the practice of physicians, physiotherapists, dieticians, and active individuals (including elite athletes), by gaining more insight into the effect of collagen supplementation on tendon protein synthesis, and thereby identifying a novel nutritional strategy that can aid in the prevention and treatment of tendon injuries.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

Planned for ACL reconstruction with hamstring or quadriceps autograft

Age  $\geq 18$  and  $\leq 40$  years.

BMI  $\geq 18.5$  and  $\leq 30$  kg/m<sup>2</sup>

### Exclusion criteria

- Blood donation during the study period or during the last 2 months
- Pregnancy
- Third generation oral contraceptives
- Consumption of  $>21$  alcoholic beverages per week
- Use of any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescribed acne

medications).

- Regular use of protein or other nutritional supplements (including vitamins).
- Reported slimming or medically prescribed diet
- Use of antibiotics in the past month
- Current participation in another biomedical research study.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-02-2024
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	26-05-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	11-09-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	

Date:	07-03-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	03-05-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL84264.096.23